

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION**

ENVIRONMENTAL DEFENSE FUND;
MONTANA ENVIRONMENTAL
INFORMATION CENTER; and CITIZENS
FOR CLEAN ENERGY,

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; and ANDREW R. WHEELER, in
his official capacity as Administrator of
the U.S. Environmental Protection
Agency,

Defendants.

Case No.: 4:21-cv-00003-BMM

The Honorable Brian Morris,
Chief Judge

**PLAINTIFFS' REPLY IN SUPPORT OF MOTION
FOR PARTIAL SUMMARY JUDGMENT**

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INTRODUCTION

When it published the challenged rule, the EPA claimed that it could demonstrate “good cause” to dispense with the 30-day notice period required by section 553(d) based on the rule’s “crucial” role in “ensuring confidence in EPA decision-making.” But, faced with this lawsuit, the EPA now makes no effort to defend that good-cause finding. Indeed, the agency offers no reason at all for its decision to deprive the public of notice during this period of presidential transition. The EPA instead falls back on its alternative position that this rule is “merely procedural”—that is, that this sweeping, controversial rule that the agency spent two and a half years developing, subjected to notice-and-comment rulemaking, and that garnered almost a million public comments—is just an “internal house-keeping measure[],” *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980), and thus entirely exempt from section 553(d).

The EPA’s rule is far from the sort of routine housekeeping measure that Congress intended to exempt from the APA’s rulemaking procedures. By fundamentally altering the ways in which the EPA can permissibly rely on key scientific research, the rule—in the agency’s own words—has “the potential to impact all future significant regulatory actions and influential scientific information that rely on dose-response data.” EPA, *Final Rule - Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information*,

<https://perma.cc/7Y8B-M6L9> (last visited Jan. 21, 2021). The rule imposes significant effects by hampering the ability of private parties, like the plaintiffs, to rely on important scientific research in advocating for safeguards and in petitioning the agency to take specific actions. It impacts the substantive standards that the EPA will adopt in the future, by restricting the scientific studies on which the EPA may base final significant regulatory actions. It thus inevitably impacts not only regulated parties but the public health as well. And it binds the EPA itself with the force of law. The rule, in short, is substantive, not procedural, and hence subject to section 553(d)'s 30-day notice mandate.

The government's attempt to defeat the plaintiffs' standing fares no better. All three plaintiffs have standing to challenge the EPA's decision to disregard the 30-day requirement because that decision deprives them of the opportunity to petition the EPA to "postpone" the rule's effective date under section 705. In response, the EPA confusingly claims that the plaintiffs can still petition to change the rule's effective date under section 553(e), which gives any "interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e). But that argument hinges on the government's mistaken position on the merits that this rule is "procedural." A substantive rule cannot be postponed once it has gone into effect. *See Nat. Res. Def. Council v. U.S. Dep't of Energy*, 362 F. Supp. 3d 126, 151 (S.D.N.Y. 2019).

And the government simply ignores the wide array of concrete financial, professional, and organizational interests identified in the plaintiffs' declarations.

Because the EPA lacked any valid basis to avoid the notice mandated by the APA, the Court should declare that the challenged rule will not become effective until February 5, 2021, as required by section 553(d). And, to ensure that the plaintiffs have adequate time to petition the EPA and obtain a response before the rule becomes effective, we respectfully request that the Court grant a partial final judgment under Rule 54(b) by January 28, 2021—a request the EPA has not opposed.

ARGUMENT

I. The EPA's rule is a substantive restriction on the agency's discretion and thus subject to the 30-day notice requirement.

The EPA makes no effort to defend its purported finding that it had “good cause” to dispense with section 553(d)'s 30-day notice requirement. Instead, the agency relies only on its alternative position that its sweeping rule is “procedural,” and thus exempt from section 553(d), because it is just an “internal house-keeping measure[] organizing agency activities.” *Batterton*, 648 F.2d at 702.

The EPA's rule, however, has none of the marks of internal housekeeping. The agency spent two and a half years developing the rule, subjected it to notice-and-comment rulemaking, and received almost one million public comments. And its final rule amends the Code of Federal Regulations to add significant new restrictions on the agency's discretion to rely on key scientific research—restrictions

that the agency says are “crucial for ensuring confidence in EPA decision-making.” *Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information*, 86 Fed. Reg. 469, 472 (Jan. 6, 2021). Those restrictions, as the agency puts it, have “the potential to impact all future significant regulatory actions and influential scientific information that rely on dose-response data.” EPA, *Final Rule - Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information* (last visited Jan. 21, 2021), <http://bit.ly/2NfZ24Y>.

Indeed, the EPA’s original notice of proposed rulemaking did not even claim that the rule was procedural; only in its supplemental notice did the agency, in an attempt to fit its rulemaking into the confines of its claimed housekeeping authority, assert that the rule was an “internal rule of agency procedure” exempt from the APA’s procedural requirements. *Strengthening Transparency in Regulatory Science*, 85 Fed. Reg. 15396, 15398 (supplemental notice proposed Mar. 18, 2020). Its justification for doing so—both in its rulemaking and in this Court—is its claim that the rule does not “alter the rights or interests of parties” outside of the agency itself. *JEM Broad. Co. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994) (citation omitted). For several reasons, the agency is wrong.

A. To begin with, the EPA’s rule *does* “produce ... significant effects on private interests,” *Batterton*, 648 F.2d at 702, by hampering the ability of third parties to rely

on important scientific research in advocating for safeguards and in petitioning the agency to take specific actions. That is precisely the sense in which the D.C. Circuit held in *CropLife America v. EPA* that the agency's action bound third parties there. 329 F.3d 876, 881 (D.C. Cir. 2003). The EPA in *CropLife* had issued a press release announcing that it would no longer consider third-party human studies submitted for consideration in rulemaking. *Id.* Such a rule, the court held, was "binding on petitioners" because it prevented their reliance on those studies, "even in cases where such studies formerly were approved." *Id.* The same is true here. The agency itself recognizes that, "[a]cross EPA programs, much of the science that informs regulatory actions is developed outside the Agency." *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18768, 18769, 18770 (proposed Apr. 30, 2018). Its rule is thus of "interest to entities that conduct research and other scientific activity that is likely to be relevant to EPA's regulatory activity." *Id.* Those outside parties can no longer count on the studies they submit receiving serious agency consideration.

Moreover, by restricting the scientific studies on which the EPA may base final significant regulatory actions, the rule inevitably impacts the substantive standards that the EPA will adopt in the future, thus affecting not only regulated and other interested parties but the public health as well. Indeed, the whole point of the rule is to affect the substance of the EPA's decisionmaking. As the agency has explained, the rule will affect the "most impactful" and "significant" EPA regulatory actions—

actions that will have “a clear and substantial impact on important public policies or private sector decisions.” 86 Fed. Reg. 473, 474. A rule like this, which alters the agency’s consideration of science with “the intent and effect of changing substantive outcomes,” is a “substantive” rule subject to section 553(d)’s mandatory 30-day notice period. *Am. Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1047–48 (D.C. Cir. 1987).

B. In any event, a rule need not affect parties outside the agency to be “substantive” under the APA. As our opening brief explained, a rule can be “substantive” not only when it affects private parties, but also when it “binds ... *the agency itself*.” *CropLife Am.*, 329 F.3d at 883 (emphasis added). The “critical factor” is “the extent to which the [rule] leaves the agency ... free to exercise discretion to follow, or not to follow” the rule “in an individual case.” *Colwell v. Dep’t of Health & Hum. Servs.*, 558 F.3d 1112, 1124 (9th Cir. 2009); *see also Mun. of Anchorage v. United States*, 980 F.2d 1320, 1324–25 (9th Cir. 1992). “A properly adopted substantive rule establishes” a new “binding norm”—a “standard of conduct which has the force of law” in subsequent rulemaking. *Pac. Gas & Elec. Co. v. Fed. Power Comm’n*, 506 F.2d 33, 38–39 (D.C. Cir. 1974). An EPA rule that limited the circumstances in which the agency could enact future pollution limits, for example, would plainly be substantive because, even if it did not directly affect the rights of third parties, it would still impose a new, substantive limit on the agency’s discretion.

The EPA complains (at 3) that treating rules that bind agency personnel as substantive would mean that “all interpretive rules, which explain agencies’ constructions of statutes they regulate and advise the public of how they are likely to apply them, would require notice-and-comment rulemaking and delayed effective dates.” On this point, the agency is simply confused. Interpretative rules are not, as the agency assumes, necessarily “procedural.” See Thomas W. Merrill & Kathryn T. Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 Harv. L. Rev. 467, 477 (2002); *Joseph v. U.S. Civ. Serv. Comm’n*, 554 F.2d 1140, 1153 n.24 (D.C. Cir. 1977). Such rules are categorically excluded from section 553(d)’s 30-day notice requirement not because they are procedural but because section 553(d)(2) specifically exempts “interpretative rules.” 5 U.S.C. § 553(d)(2); see also *id.* § 553(b)(A) (exempting “interpretative rules” from notice-and-comment requirements). The EPA does not claim that its rule falls within that express exemption here. See 86 Fed. Reg. 472 (the rule “does not interpret ... provisions of a particular statute or statutes”). And if, as the agency suggests, interpretative rules were all “procedural” within the meaning of section 553(d), the exemption would be superfluous.¹

¹ The EPA’s reliance (at 30) on the Ninth Circuit’s decision in *Hemp Industries* is rooted in the same confusion. *Hemp Industries* is not about distinguishing between substantive rules and procedural ones. It is about distinguishing between legislative and interpretative rules—both of which, again, can be “substantive” rules under section 553(d). *Pac. Gas & Elec. Co.*, 506 F.2d at 39. *Hemp Industries* thus does not, and could not, support the EPA’s argument that its rule is “merely procedural.”

C. Here, the EPA’s rule binds the agency’s discretion and is therefore a “substantive rule” subject to section 553(d). The reason is straightforward: Before the rule, the agency had discretion to give equal weight to the best available scientific research in developing new regulations, regardless of whether a study’s underlying clinical data was available. Now, the agency lacks that discretion. The rule provides that the agency “*shall* give greater consideration” to studies where underlying data is available, and otherwise “*will* give [studies] lesser consideration.” 86 Fed. Reg. 492 (to be codified at 40 C.F.R. § 30.5) (emphasis added). The rule thus “effectively replaces agency discretion with a new ‘binding rule of substantive law’”—one in which important epidemiological studies will be entitled to reduced consideration in rulemaking. *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013–14 (9th Cir. 1987).

CropLife is once again directly on point. As in *CropLife*, the EPA’s rule here restricts its own discretion to consider studies in “clear and unequivocal language” that reflects “an obvious change in established agency practice.” *CropLife Am.*, 329 F.3d at 881. And, also as in *CropLife*, the EPA has thus “clearly establishe[d] a substantive rule.” *Id.* at 883. If anything, the rule here is more clearly substantive. The EPA’s challenged action in *CropLife* was its issuance of an informal press release announcing its intent to limit future consideration of third-party studies. *See id.* Here, by contrast, the agency subjected its limits to formal notice-and-comment rulemaking and published those limits in the Code of Federal Regulations—further

evidence of the agency’s intent to imbue its rule with binding effect. *See Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 19 (D.C. Cir. 2019); *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993).

The EPA argues (at 25–26) that *CropLife* is “inapposite” because its rule here “does not require EPA employees to reach a particular result in any particular rulemaking.” But neither did the press release in *CropLife*. As here, the EPA in *CropLife* just required the agency to discount particular studies in its rulemaking, not to adopt particular rules. The agency also attempts (at 25) to distinguish *CropLife* on the ground that the “legal consequences” there were “binding on *both* petitioners and the agency,” whereas the rule here binds only the agency. Under *CropLife*, however, an agency action need only “bind[] private parties *or* the agency itself” to be substantive; it need not bind both. *CropLife Am.*, 329 F.3d at 883 (emphasis added). And in any event, as explained above, the press release in *CropLife* had the same effect on third parties as the EPA’s rule here—in both cases restricting the EPA’s discretion to consider certain studies submitted by third parties.

D. The EPA disputes the binding nature of its rule for several reasons. It first claims that its rule “simply provides instruction to EPA employees on the relative weight it *should* afford certain studies in certain rulemakings.” EPA Br. 26 (emphasis added). But the rule does not merely suggest that the EPA “should” afford different weight to studies based on the availability of the underlying data—it provides, with

the force of law, that the agency “shall” do so. 86 Fed. Reg. 492 (to be codified at 40 C.F.R. § 30.5). “Unlike the word ‘may,’ which implies discretion, the word ‘shall’ usually connotes a requirement.” *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016). And where a rule, as here, is “couched in mandatory language, ... a binding intent is strongly evidenced.” *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002).

The agency next argues (at 4) that, “regardless of the relative weight EPA assigns to particular studies, it must review and evaluate *all* relevant scientific studies when developing significant regulatory actions and influential scientific information.” But although it is true that the agency is required to “review and evaluate” such studies as a first step, it is then required to give “lesser consideration” to those studies for which underlying data is not available. That requirement does not “merely provide[] *guidance* to agency officials in exercising their discretionary powers while preserving their flexibility and their opportunity to make individualized determinations.” *Mada-Luna*, 813 F.2d at 1013 (emphasis added). Nor does it leave those officials “free to consider the individual facts in the various cases that arise.” *Id.* at 1014. Rather, it establishes a “binding norm,” “narrowly limit[ing] administrative discretion” such that “one need only determine whether a given case is within the rule’s criteri[a]” to determine the weight a study is due. *Id.* By “specifying factors it considers in exercising its discretion,” the EPA “effectively

directed the focus of the [agency’s] discretionary judgment.” *Batterton*, 648 F.2d at 707.

Finally, the agency contends (at 26) that the rule is just a non-binding “policy statement[]” because it “provides substantial discretion on the part of the Administrator to waive the rule’s requirements, on a case-by-case basis.” Unlike a non-binding statement of policy, however, the rule does not leave either the agency or the Administrator “free to exercise ... informed discretion.” *Panhandle Producers & Royalty Owners Ass’n v. Econ. Regul. Admin.*, 822 F.2d 1105, 1110 (D.C. Cir. 1987). Rather, the rule limits the Administrator’s exercise of discretion to specific, substantive waiver criteria that must be documented in the record and can be subjected to judicial review. 86 Fed. Reg. 493 (to be codified at 40 C.F.R. § 30.7); *see also id.* at 487 (reciting the “boundaries” the rule imposes on that discretion). To exercise that discretion is not, as the agency claims (at 4), “to waive the rule’s requirements altogether on a case-by-case basis”—it is just to apply those requirements to specified circumstances. That the rule allows exemptions in carefully delineated circumstances “does not undermine the binding force of the [rule] in standard cases.” *Gen. Elec. Co.*, 290 F.3d at 384; *see McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1321 (D.C. Cir. 1988) (holding that a rule’s “provision for exceptions” did not “push it much in the direction of a policy statement”). At most, the exemptions speak to the rule’s reasonableness, not its substantive character.

II. The EPA fails to rebut the plaintiffs’ detailed showing of their standing to challenge the rule’s effective date.

A. The plaintiffs have standing based on their procedural injuries.

1. As our opening brief explained (at 28–41), the plaintiffs have standing to challenge the agency’s decision to forgo compliance with section 553(d)’s 30-day notice requirement because the decision deprives them of the opportunity to petition the EPA to “postpone” the rule’s effective date under section 705 of the APA to allow time for a judicial challenge and agency reconsideration. The government responds (at 16–17) that the plaintiffs “have not lost the opportunity to petition” the agency because they could still petition to change the rule’s effective date under section 553(e), which gives any “interested person the right to petition for the issuance, amendment, or repeal of a rule.” 5 U.S.C. § 553(e).

That argument, though the EPA does not acknowledge it, depends on the agency’s conclusion on the merits that its rule is “procedural.” That’s because a rule cannot be postponed under section 705 once it has already gone into effect. *See Nat. Res. Def. Council*, 362 F. Supp. 3d at 151; *Nat. Res. Def. Council v. Nat’l Highway Traffic Safety Admin.*, 894 F.3d 95, 113 (2d Cir. 2018). If the agency were correct that its rule is procedural, it might nevertheless be able to amend the rule—including its effective date—without following the APA’s notice-and-comment requirements. *See* 5 U.S.C. § 553(b)(A) (exempting procedural rules from that requirement). But because, as

explained above, the rule is in fact substantive, the agency lacks that option here. The plaintiffs would thus instead have to petition the agency to amend the rule pursuant to notice-and-comment rulemaking—a process that would take at least months and likely much longer. *See Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1484 (9th Cir. 1992). The plaintiffs’ inability to seek immediate postponement, as they could if the agency had followed its obligation under section 553(d), is precisely the injury for which they are seeking relief in this Court, and that injury would not be remedied by subjecting themselves to the rule while the EPA undertakes new notice-and-comment rulemaking.²

And even if the substantive nature of the rule were in doubt, the EPA’s effort to contest a merits point has no place in this Court’s standing analysis, which must presume the plaintiffs will prevail on the merits. *See Stop the Beach Renourishment, Inc. v. Fla. Dep’t of Env’t. Prot.*, 560 U.S. 702, 729 n.10 (2010); *United States v. Antelope*, 395 F.3d 1128, 1133 (9th Cir. 2005).

B. The EPA next questions the plaintiffs’ right to obtain postponement, arguing (at 17) that “it is not apparent” that section 705 “is even intended to protect the interests of Plaintiffs as opposed to agencies.” It is abundantly clear from section

² The plaintiffs did not, as the agency asserts (at 17), “forgo” the “procedural avenue” provided by section 553(e). They *would* file such a petition to postpone the rule’s effective date, but they cannot obtain postponement of a rule already in effect. The requested relief is thus a prerequisite for their exercise of their procedural rights.

705, however, that the section is designed to do just that. The section gives the agency authority to postpone a rule only “pending judicial review.” 5 U.S.C. § 705. Such a postponement obviously protects the interests of those who, like the plaintiffs here, have brought a legal challenge to the rule and wish to seek postponement of the rule during the pendency of that challenge. Moreover, the section ties the agency’s authority to postpone such a rule to a “find[ing] that justice so requires,” *id.*—an equitable standard that necessarily takes into account harm not just to the agency, but also to the plaintiffs challenging the rule (and to others who would be affected by it). *See California v. U.S. BLM*, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017) (“If the words ‘justice so requires’ are to mean anything, they must satisfy the fundamental understanding of justice: that it requires an impartial look at the balance struck between the two sides of the scale.”).

C. Finally, the EPA argues (at 16) that the plaintiffs “have identified no concrete injury that they contend will ensue as a result of the lack of the opportunity to request a later effective date for the Final Rule.” That assertion is patently incorrect, ignoring the lengthy list of immediate harms to concrete interests the plaintiffs identified in their opening brief and documented in their supporting declarations. Instead, the EPA’s brief (at 17–18) knocks down a strawman: The concrete interest underlying the plaintiffs’ procedural injury, the agency says, is limited to the right to file a petition seeking a postponement of the rule’s effective

date—but because that right is merely procedural, it can’t constitute a concrete interest.

That’s not the plaintiffs’ argument. As explained above and as outlined in our opening brief (at 30–31), the plaintiffs have a procedural right to petition the EPA for a postponement of the effective date of the rule under section 705 of the APA. And as the plaintiffs (at 32–38) and their declarants have laid out in painstaking detail, the right to petition for a postponement protects concrete interests that are otherwise harmed by the rule’s immediate effective date. EDF member-scientists’ financial interests, for instance, will be immediately impacted by the need to adapt and restructure current applications for grant funding from the National Institutes of Health (NIH)—or devote further resources to cohort recruitment—to respond to the effects of the rule. *See, e.g.*, Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19. Those scientists’ professional interests in pursuing their intended research agendas, working with underserved communities, and informing policymaking are similarly immediately and directly impacted—as are the plaintiffs’ organizational interests in incorporating science to which the EPA will accord full weight in its decision-making.

The EPA ignores all this. It treats the plaintiffs’ financial, professional, and organizational interests as pertaining only to their *substantive* injuries-in-fact. And having adopted that framework, the government dismisses the wide array of threats

to plaintiffs’ concrete interests as depending on a long “chain of speculative assumptions” and as being “self-inflicted” or “purely voluntary.” EPA Br. 18, 20–21. It is mistaken in both respects.

To begin with, none of the plaintiffs’ standing theories depend on satisfying each of the links in the “chain” the EPA purports to identify. *First*, the government ignores the plaintiffs’ ample evidence that EDF member-scientists’ work does depend on dose-response data that cannot be submitted for independent verification—whether because of the nature of the data or the concerns of the vulnerable communities with whom the scientists work. *See, e.g.*, Sarnat Decl. ¶¶ 7, 9–11; J. Lewis Decl. ¶¶ 21, 23, 25; Balmes Decl. ¶ 16. *Second*, the government misunderstands the relationship between NIH grant funding, EPA decision-making, and EDF member-scientists’ work. The immediate risk EDF member-scientists face is that grant-funding entities like NIH institutes will *anticipate* that the EPA will afford the scientists’ work less weight and accordingly be less likely to award them grant funding. Plaintiffs don’t simply speculate that this will occur—they offer a declaration from the former Director of the National Institute of Environmental Health Science, who explains that, in her experience, research that is “unlikely or unable to be used to inform EPA decisionmaking” or will receive “limited weight in that decisionmaking” is “unlikely” to be funded. Birnbaum Decl. ¶ 13. This means that EDF member-scientists face difficulties securing grant funding *regardless* of what rule-making the EPA undertakes

in the future, what waivers the EPA grants, and what weight the EPA ultimately accords their research.

And *third*, the EPA suggests these consequences will materialize at some indeterminate date in the future. But that argument ignores plaintiffs’ evidence that numerous EDF member-scientists face these consequences *now*. Members currently preparing grant applications or recruiting cohort participants must presently spend precious resources understanding the impact of the rule, redesigning their studies, revising applications, and communicating with research cohorts. All these consequences are at least “reasonably probable,” which is all that is needed for an Article III injury. *See California v. Azar*, 911 F.3d 558, 570 (9th Cir. 2018).

Even if the EPA were correct that there were some uncertainties as to exactly when or how the concrete interests of the plaintiffs and their members will be affected, that would have no bearing on whether the plaintiffs had shown standing based on their *procedural* injury-in-fact. As we explained in our opening brief (at 39–41), that injury is subject to relaxed causation and redressability standards—which are plainly met here.³

³ Indeed, just yesterday the White House issued a memorandum imposing a “regulatory freeze” and ordering a review of rules yet to take effect. Ronald A. Klain, *Regulatory Freeze Pending Review* (2021), <https://perma.cc/66HX-QG9A>. That the new administration is subjecting not-yet-effective rules to close scrutiny suggests that there is at least “some possibility” that it would grant the plaintiffs’ petition to immediately postpone the rule’s effective date. *See Massachusetts v. EPA*, 549 U.S. 497, 518 (2007).

Nor are measures the plaintiffs and their members take to adapt to this reality self-inflicted, because the costs of the rule are inescapable. When millions of dollars of grant funding are on the line, and the EPA has promulgated a rule that radically shifts the market for research science, EDF member-scientists have no choice but to assess the impact that shift has on their work. *See* Sarnat Decl. ¶¶ 7, 9–11; J. Lewis Decl. ¶¶ 15, 25; Balmes Decl. ¶ 17. That assessment itself is costly, especially to scientists who must submit grant applications or recruit new cohort participants coming weeks—a group of EDF members the EPA’s brief ignores entirely. And scientists have no way to avoid the rule’s effects: Either they risk losing grant funding, or they must accept the financial and professional consequences of conducting either rule-compliant research that fails to preserve subject confidentiality, or non-compliant research that adopts second-rate methods and is unlikely to inform key policymaking decisions. Sarnat Decl. ¶¶ 5–6, 8, 11, 13–16; J. Lewis Decl. ¶¶ 19, 23, 25–26, 29; Balmes Decl. ¶¶ 4, 15–19. Moreover, the disclosures scientists must make to research subjects—that their work either cannot preserve confidentiality or will be less likely to receive weight in EPA decision-makings—risk undermining delicate trust relationships, immediately impacting EDF members’ ability to recruit and retain research subjects and to conduct the scientific research they entered their fields to pursue. *See* J. Lewis ¶¶ 17–19, 28–29; Balmes Decl. ¶¶ 12, 18. The EPA does not dispute these critical points.

At bottom, the EPA seems to misunderstand the plaintiffs’ point: Scientists *can’t* avoid the costs of the rule because they must adapt their work or risk profound financial, professional, and personal consequences—and, without a postponement of the rule, they must do so immediately. If the plaintiffs’ members will suffer consequences regardless of what they do, those consequences are neither speculative nor self-inflicted.

The government’s arguments are similarly unconvincing when directed against the plaintiffs’ organizational interests. Like their member-scientists, plaintiffs have no choice but to examine the effects of the rule on their advocacy and adapt that advocacy to the EPA’s new requirements—a process that will impose unavoidable costs. *See* McPartland Decl. ¶¶ 15–22, Hedges Decl. ¶ 9; Liebert Decl ¶ 8.

* * *

Accordingly, the plaintiffs have demonstrated standing based on the deprivation of their procedural right to petition for a postponement of the rule’s effective date. The loss of that right amounts to a cognizable procedural injury-in-fact arising from immediate harms to plaintiffs’ concrete interests, and that injury easily satisfies the “[r]elaxed” traceability and redressability requirements that apply to injuries like it. *California*, 911 F.3d at 571.

B. The plaintiffs’ additional, substantive injuries provide an independent basis for their standing.

Even when framed as an objection to the plaintiffs’ independent showing of a substantive injury-in-fact, the government’s arguments still come up short. As we explained in our opening brief (at 38–39), this injury is based on the fact that the rule imposes immediate financial expenses on EDF members facing imminent grant deadlines or rounds of cohort recruitment.

The EPA’s brief never addresses these injuries, but its blanket argument that they are “speculative” and “self-inflicted” is no more convincing in this context than it was above. Indeed, it requires no speculation at all to understand that numerous EDF member-scientists face the immediate and unavoidable cost of trying, at the last minute, to understand the rule’s impact on their research proposals and on the likelihood of obtaining funding and scrambling to adapt their proposals and cohort recruitment accordingly. *See* Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 17–18. There is therefore at least a “substantial risk” that EDF member-scientists will face the injury they fear. *See Index Newspapers v. U.S. Marshals Serv.*, 977 F.3d 817, 825 (9th Cir. 2020) (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)). And it is the very nature of a double-bind that those in it face costs whatever they do. Such costs are concrete and particularized to the specific member-scientists who face them, and they are actual or imminent in light of the immediate turnaround they unavoidably require. *See Friends of the Earth, Inc. v. Laidlaw Env’t Servs.*

(*TOC*), *Inc.*, 528 U.S. 167, 180–81 (2000). And, as explained in our opening brief (at 41–42), they are traceable to an immediate effective date that deprives the affected scientists from the opportunity to prepare—as well as redressable by a timely and favorable decision by this court.

For these reasons, the plaintiffs’ members have experienced substantive as well as procedural injuries-in-fact and, on that basis, have standing to challenge the rule.

CONCLUSION

The plaintiffs’ motion for partial summary judgment should be granted, and the Court should enter partial final judgment to that effect under Rule 54(b).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 21, 2021, I electronically filed this reply brief in support of the plaintiffs' motion for partial summary judgment through this Court's CM/ECF system. I understand that notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

January 21, 2021

/s/ Deepak Gupta
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